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APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,024 09/0		09/07/2001	Gerald Wayne Becker	X-12799	9679
25885	7590	03/10/2003		`	
ELI LILLY AND COMPANY PATENT DIVISION P.O. BOX 6288				EXAMINER	
				O HARA, EILEEN B	
INDIANAPOLIS, IN 46206-6288				ART UNIT	PAPER NUMBER
				1646	-
				DATE MAILED: 03/10/2003	DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
		09/936,024	BECKER ET AL.				
	Office Action Summary	Examiner	Art Unit				
		Eileen O'Hara	1646				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address							
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any eamed patent term adjustment. See 37 CFR 1.704(b).							
Status	Decreasing to communication (a) filed as 40.5	No					
1)[Responsive to communication(s) filed on 10 E						
2a)☐	,—	is action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4)⊠	Claim(s) 1-9,11 and 13-15 is/are pending in th	e application.					
4a) Of the above claim(s) <u>1-6,11 and 13-15</u> is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>7-9</u> is/are rejected.							
7)	7) Claim(s) is/are objected to.						
8) Claim(s) 1-9,11 and 13-15 are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11)∐ T	11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.							
12)☐ The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
	1. Certified copies of the priority documents have been received.						
2	2. Certified copies of the priority documents have been received in Application No						
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
2) Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal F	(PTO-413) Paper No(s) Patent Application (PTO-152)				

DETAILED ACTION

1. Claims 1-9, 11 and 13-15 are pending in the instant application.

Election/Restrictions

2. Applicant's election of claims 7-9, corresponding to FLINT analog of SEQ ID NO:1, in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a). The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6, 11 and 13-15 are withdrawn as being drawn to a non-elected invention.

Claims 7-9 are currently under examination.

Priority

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application

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has become a patent, the expression "now Patent No. _____" should follow the filing date of the

parent application. If a parent application has become abandoned, the expression "now

abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a0 on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay

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was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

Specifically, the blank space on the forth line after the title should be filled in with 60/183,398.

Specification

4. The disclosure is objected to because of the following informalities: there are two figures in the application, but there is no section entitled "Brief Description of the Drawings" or figure legends.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 5. Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- Claims 7-9 are vague and indefinite because of the term "defined by". It is not clear what this term means, and if it encompasses a polypeptide fragment consisting of just the amino acids recited, or if it encompasses a larger polypeptide comprising those amino acids.
- 5.2 Claims 7 and 8 are also vague and indefinite because it appears that they are both claiming the same polypeptide fragment of the same length the claims appear to be duplicative.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 6.1 Claims 7-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Masiakowski et al., WO 99/07738, Feb. 18, 1999, Pitti et al., Nature, Vol. 396, pages 699-703, December, 1998, Emery et al., US Patent No. 5,885,800, March 23, 1999, Gentz et al, WO 98/30694, July 16, 1998 or Emery et al., EP 0 861 850, Sept. 2, 1998.

Claims 7-9 encompass a FLINT analog wherein the analog is defined by residues 1-218 or 1-216 of SEQ ID NO: 1. Because the language "defined by" is indefinite, the claims as written read on a polypeptide comprising those amino acid fragments.

WO 99/07738, Pitti et al., US Patent No. 5,885,800, WO 98/30694 and EP 0 861 850 each disclose a polypeptide comprising 300 amino acids, which is identical to the polypeptide of SEQ ID NO: 1 of the instant invention over the 271 amino acids of SEQ ID NO: 1 (see attached sequence alignment). Although each of these references did not appreciate that the full length polypeptide of SEQ ID NO: 1 undergoes proteolysis in vivo to produce at least two major peptide fragments (amino acids 1-218 and 219-271), the claims as written read on the larger

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polypeptide, which is disclosed in each of the references. Therefore, each reference anticipates the claims.

6.2 Claims 7-9 are rejected under 35 U.S.C. 102(e) as being anticipated by published US Application No. 20020150583, priority date January 14, 1997 (60/035,496).

Application No. 20020150583 discloses a polypeptide (SEQ ID NO: 2) comprising 300 amino acids, which is identical to the polypeptide of SEQ ID NO: 1 of the instant invention over the 271 amino acids of SEQ ID NO: 1 (see attached sequence alignment). Although this reference did not appreciate that the full length polypeptide of SEQ ID NO: 1 undergoes proteolysis in vivo to produce at least two major peptide fragments (amino acids 1-218 and 219-271), the claims as written read on the larger polypeptide, which is disclosed in the reference. Therefore, Application No. 20020150583 anticipates the claims.

Conclusion

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

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Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

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